

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 28, 2007

Linda Hedaya ("Ms. Hedaya" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Abraham Hedaya, Ms. Hedaya's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Elliot D. Agin, M.D. Based on an echocardiogram dated November 30, 2000, Dr. Agin attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation, severe aortic regurgitation,⁴ and a reduced ejection fraction in the range of

3 (...continued)

contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Ms. Hedaya's claim does not present any of the complicating factors necessary to receive Level II Matrix Benefits for damage to her aortic valve. See Settlement Agreement § IV.B.2.c.(2)(a). A claim based solely on severe aortic regurgitation qualifies for (continued...)

50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.

In the report of claimant's echocardiogram, Scott L. Roth, M.D., F.A.C.C., the reviewing cardiologist, stated that claimant had "[m]ild to moderate mitral insufficiency," but did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Roth also estimated claimant's ejection fraction as 60%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b).

In August 2005, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Wang found that claimant's "MRJA/LAA is 14%." Dr. Wang, however, found that there was a

4 (...continued)

Level I benefits. Given our ultimate disposition of claimant's Level II claim based on damage to her mitral valve, however, claimant's level of aortic regurgitation is not relevant to this claim. See supra.

reasonable medical basis for the attesting physician's finding of a reduced ejection fraction.⁵

Based on Dr. Wang's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Hedaya's claim. Pursuant to the Rules for the Audit of Matrix Compensation Benefits ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted an expert report from Robert L. McNamara, M.D., M.H.S., F.A.C.C. In the report, Dr. McNamara stated that claimant had moderate mitral regurgitation. He further explained that "[b]y my measurements, mitral regurgitant jet area to left atrial area (RJA/LAA) is 32% (four chamber view) and 36% (two chamber view)."

The Trust then issued a final post-audit determination, again denying Ms. Hedaya's claim. Claimant disputed this final determination and requested that the claim proceed to the show

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. at § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of a reduced ejection fraction, which is one of the conditions needed to qualify for Level II benefits, the only issue is claimant's level of mitral regurgitation.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hedaya's claim.

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hedaya's claim should be paid. On February 21, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6006 (Feb. 21, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 2, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Hedaya resubmitted Dr. McNamara's expert report. Claimant argues that Dr. McNamara's finding of moderate mitral regurgitation provides a reasonable medical basis for her claim.

In response, the Trust argues that Dr. McNamara's report does not provide a reasonable medical basis for Dr. Agin's finding of moderate mitral regurgitation because Dr. McNamara does not identify multiple loops and consecutive frames that demonstrate the presence of a sustained mitral regurgitant jet occupying at least 20% of a representative left atrial area. The Trust also contends that Dr. McNamara's report does not address the auditing cardiologist's specific findings.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical

basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Burke concluded that:

Although there was considerable variability evident in the degree of mitral regurgitation among the above views, both my overall clinical impression, as well as my measurements of these views for RJA/LAA ratios, result in my conclusion that moderate mitral regurgitation is present.

... In the apical four chamber view, using representative beats, I calculated a RJA/LAA ratio of well over 20% - in the range for moderate mitral regurgitation. In the apical two chamber view, using representative beats, I calculated a RJA/LAA ratio of well over 20% - again in the range of moderate mitral regurgitation. In the apical long axis view, using representative beats, I again calculated a RJA/LAA ratio of over 40% - in the range of severe mitral regurgitation.

* * *

In conclusion, I believe there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., which states the Claimant suffers from moderate mitral regurgitation.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Agin, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation.⁸ Although the Trust challenged the attesting physician's finding, Dr. Burke confirmed that

8. Although unnecessary for resolution of this claim, as noted above, claimant also submitted an expert report of an additional cardiologist who similarly concluded that claimant had moderate mitral regurgitation.

claimant suffers from moderate mitral regurgitation.⁹ Specifically, Dr. Burke concluded that claimant's "RJA/LAA ratio [was] well over 20%."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Burke measured claimant's level of mitral regurgitation in the apical views and determined that her RJA/LAA ratio was greater than 20%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.¹⁰

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Hedaya and her spouse for Matrix Benefits.

9. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

10. Accordingly, we need not address claimant's remaining arguments.

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PRETRIAL ORDER NO.

AND NOW, on this 28th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimants, Linda Hedaya, and her spouse, Abraham Hedaya, are entitled to Matrix A, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.